

## **“Existing” Chemical SNURs, and “Articles”**

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## Thomas C. "Tom" Berger



Tom Berger is a partner at Keller and Heckman. Tom has a chemical engineering background, and his practice focuses on regulation and approval of new and existing chemicals under the U.S. Toxic Substances Control Act (TSCA) and its international counterparts in Australia, Canada, China, the European Union, Japan, Malaysia, New Zealand, the Philippines, South Korea, and Taiwan. Mr. Berger also counsels trade association clients on various matters, including environmental, product disparagement, and product defense issues. Mr. Berger has extensive experience with all aspects of TSCA, including Chemical Data Reporting (CDR) rule issues, TSCA "Work Plan Chemicals," the TSCA Inventory "reset," as well as auditing, liability, enforcement, and EPA "Audit Policy" issues.



### TSCA §5(a)(1)(A)(ii)

- Chemical-specific rule
- Published in the *Federal Register* (40 C.F.R. Part 721)
- Normally (not always...) within a few years of when PMN is “approved”
- Defines certain “significant new uses”
- Requires notifying EPA via a “SNUN” at least 90 days prior to commencing a “significant new use”

### SNUR promulgation criteria:

- Under §5(a)(2), determination that a use is a significant new use made by a rule promulgated after consideration of “all relevant factors,” including—
  - (A) projected production volume
  - (B) extent to which a use changes type or form of exposure to substance
  - (C) extent to which a use increases magnitude/duration of exposure to substance
  - (D) reasonably anticipated methods of manufacturing, processing, distribution, and disposal

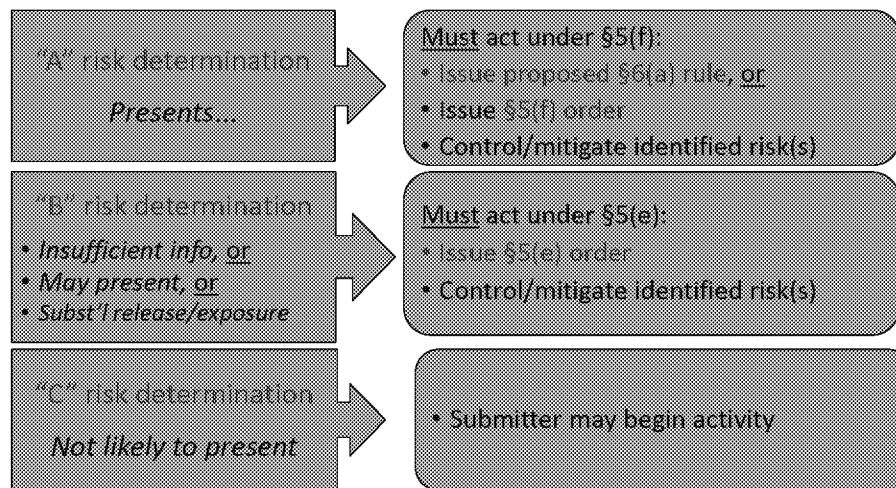
*This is not risk-based*

### **SNUN review/approval criteria:**

- Under §5(a)(3), within 90 days of receipt EPA must review SNUN and determine
  - (A) that new use presents unreasonable risk (EPA must act under §5(f))
  - (B) insufficient information or exposure/volume (EPA must act under §5(e))
  - (C) new use not likely to present an unreasonable risk (free to commence use)
- Cannot use cost/benefit
- Must evaluate under “conditions of use” (at least for (A) and (C))
- Must consider risk to identified potentially exposed or susceptible subpopulations

*This is risk-based*

# SNUN regulatory outcomes



- June 11, 2018 (83 FR 26,922)
- “Significant new use” defined as manufacture, import, or processing of asbestiform varieties of six specified fiber types for any of 15 specified uses
  - e.g., tape, millboard, adhesives, sealants, vinyl-asbestos floor tile, non-cement building materials
- “Article” exemption proposed to be inapplicable
  - except for 12(b) export notification, where article exemption applies
- “Impurity” exemption still applicable

## How can EPA regulate existing chemical with §5 SNUR?



- EPA found no evidence of ongoing uses of the 15 covered forms of asbestos as of June 1, 2018
  - Annual U.S. asbestos consumption peaked in 1973 at ~800,000,000 kg
  - Asbestos not mined/produced in U.S. since 2002; only imported (~300,000 kg/y)
    - Brazil, Russia
- Recall SNUR promulgation standard is not risk-based
  - Requires no extensive evaluation of hazard, exposure, or risk
- In this case, EPA believes that commencement of manufacture/import would increase production volume and magnitude/duration of exposure
  - SNUR promulgation criteria therefore satisfied



## Examples of Existing Chemicals with SNURs



- Certain perfluoro-chemicals (3/11/2002) (1/1/2001 ban)
  - 3M phaseout SNUR
- Additional perfluoro-chemicals (12/9/2002) (1/1/2001, 1/2003 ban)
- Polybrominated diphenylethers (PBDEs) (6/13/2006) (1/1/2005 ban)
  - Great Lakes Chemical
  - Proposed amendment 4/2/2012
- Long chain perfluoroalkyl carboxylates (LCPAC) (10/22/2013) (partial carpet ban)
  - Proposed amendment 1/21/2015
- Benzidine-based substances; and *alkanes*,  $C_{12-13}$ , *chloro-* (SCCP) (12/29/2014) (full ban on SCCP)
- Toluene Diisocyanate (TDI) (1/15/2015) (proposed) (partial consumer product ban)
- Hexabromocyclododecane (HBCD) (9/23/2015) (partial consumer textile ban)
- Trichloroethylene (TCE) (many consumer products)
- Alkylpyrrolidones (“NEP” and “NiPP”) (proposed) (partial ban of NEP)
- Asbestos (6/11/18) (proposed) (ban on 15 specified uses)

**An “article” is an item that:**

- 1) Is formed to a specific shape or design during manufacture; and
- 2) Has end-use function(s) dependent in whole or in part upon its shape or design during end use; and
- 3) Either has no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described at 40 C.F.R. § 720.30(h)(5)

- Substances **imported** into the U.S. as part of an article are exempt from PMN reporting requirements, and, therefore, are not required to appear on the TSCA Inventory
  - 40 C.F.R. § 720.22(b)(1)
- Substances *formed* during **manufacture** of an article destined for U.S. commerce without certain further chemical changes also exempt from TSCA 5 PMN reporting requirements
  - 40 C.F.R. § 720.30(h)(6)

- In original 1984 SNUR rule, EPA indicated that articles generally exempt from SNURs
  - 40 C.F.R. 721.45(f) promulgated
  - “Minimal” rationale: “...people and the environment will generally not be exposed to substances in articles.”
- But EPA “may decide to eliminate one or all of these . . . exemptions if EPA decides that review under a SNUR is warranted for specific substances . . . in articles.”

## **Pre-LCSA examples of SNURs without “article” exemption**

- Erionite fiber, 56 Fed. Reg. 56,472 (Nov. 5, 1991)
- Elemental mercury, 77 Fed. Reg. 31,728 (May 30, 2012)
- Benzidine-based chemical substances, 79 Fed. Reg. 77,891 (Dec. 29, 2014)
- Toluene diisocyanate (TDI), 80 Fed. Reg. 2,068 (Jan. 15, 2015) (proposed)
- Certain perfluorinated substances, 80 Fed. Reg. 2,885 (Jan. 21, 2015) (proposed)
- Hexabromocyclododecane and 1,2,5,6,9,10-hexabromocyclododecane (HBCD), 80 Fed. Reg. 57,293 (Sep. 23, 2015) (imported/processed textiles only)

- Prior to TSCA reform, section 720.45(f) could be rendered inapplicable by EPA simply *deciding* that SNUR review warranted for specific substance
- New LCSA §5(a)(5):
  - *[EPA] may require notification . . . for the import or processing of a . . . substance as part of an article . . . if the Administrator makes an affirmative finding in a rule . . . that the reasonable potential for exposure to the . . . substance through the article . . . subject to the rule justifies notification...."*
  - To this extent, now more difficult for EPA to regulate articles in the SNUR context

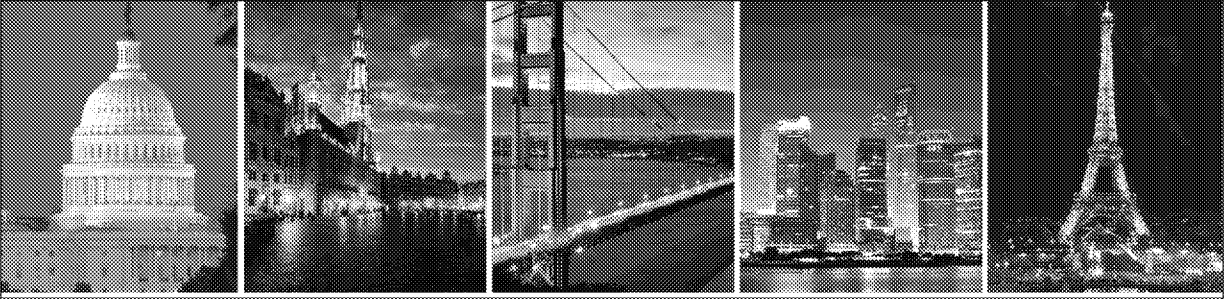
## **“Article” exemption in asbestos SNUR**



- Non-friable asbestos can become friable during use
- Asbestos fibers can be released from articles disturbed during repair/demolition
- Thus, due to reasonable potential of exposure to asbestos, §5(a)(5) is satisfied
  - 83 Fed. Reg. at 26,928
- This was/is first post-LCSA attempt to exclude articles from a SNUR

- Would expect EPA to continue to issue SNURs for (long) existing chemicals
  - As §6 stop gap, and/or in phase-out situations
- Article exemption rarely if ever inapplicable for SNURs that stem from PMNs
  - sometimes limited to certain types of articles/uses





# THANK YOU!

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